



HIE TOOLS – USER GUIDE



LIST OF REVISIONS

REVISION No.	DATE	REVISED BY:	PAGE/S	DESCRIPTION
1	TBD	GDSP	13	Initial Version



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INTRODUCTION

The purpose of this document is to provide an encompassing description of the usage of the HIE Tools, an utility to test the data exchanged between GDSP and health care provider through Newborn Screening (NBS) Results Health Information Exchange (HIE) interface. HIE Tools has features to test both the NBS HL7 Result message authored by GDSP as well as the HL7 Acknowledgement generated by the health care provider.

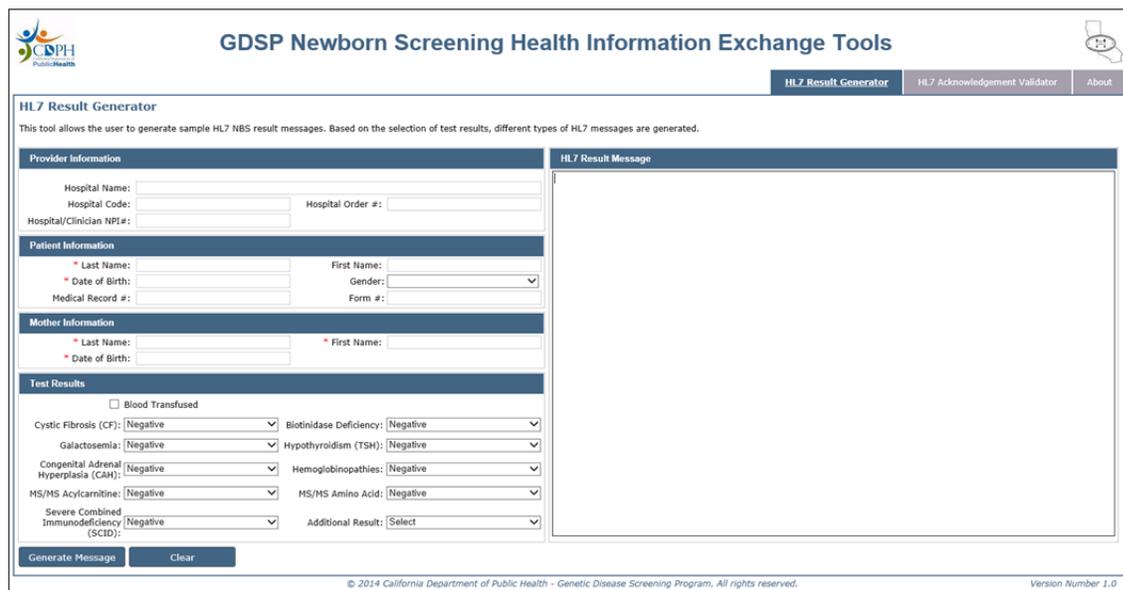
HIE tools will allow new health providers to get quickly on-boarded to Health Information Exchange (HIE) Program by GDSP.

Currently, HIE Tools include the following features:

- **HL7 Result Generator** – Generate sample NBS HL7 Result messages
- **HL7 Acknowledgement Validator** – Validate the HL7 acknowledgement (ACK) messages

Tool	URL
HL7 Result Generator	https://hiegatewaystag.cdph.ca.gov/GDSPHL7Tools/HL7Message/HL7Generator
HL7 Acknowledgement Validator	https://hiegatewaystag.cdph.ca.gov/GDSPHL7Tools/HL7Message/HL7ACKNACKValidator

Table 1: HIE Tools location



The screenshot shows the 'HL7 Result Generator' interface. It includes a header with the CDPH logo and the title 'GDSP Newborn Screening Health Information Exchange Tools'. Below the header, there are tabs for 'HL7 Result Generator', 'HL7 Acknowledgement Validator', and 'About'. The main content area is titled 'HL7 Result Generator' and contains a form with the following sections:

- Provider Information:** Hospital Name, Hospital Code, Hospital Order #, Hospital/Clinician NPI#.
- Patient Information:** Last Name, Date of Birth, Medical Record #, First Name, Gender, Form #.
- Mother Information:** Last Name, Date of Birth, First Name.
- Test Results:** Blood Transfused (checkbox), Cystic Fibrosis (CF), Galactosemia, Congenital Adrenal Hyperplasia (CAH), MS/MS Acycarnitine, Severe Combined Immunodeficiency (SCID), Biotinidase Deficiency, Hypothyroidism (TSH), Hemoglobinopathies, MS/MS Amino Acid, and Additional Result (Select).

At the bottom of the form, there are 'Generate Message' and 'Clear' buttons. The footer contains the copyright notice: '© 2014 California Department of Public Health - Genetic Disease Screening Program. All rights reserved.' and 'Version Number 1.0'.

Figure 1: HIE Tools interface

1.0 NBS HL7 RESULT GENERATOR

NBS HL7 Result Generator is a tool to generate sample HL7 messages which resemble the actual NBS results sent through Health Information Exchange (HIE) interface. The sample messages contain the newborn screening results in HL7 2.5.1 format. Refer specifications described in the section 3.0 of *HIE NBS Data Exchange Specification.docx* document from the *Step 2 - Implementation* onboarding packet.

HL7 Result Generator tool allows user to generate a variety of NBS HL7 results. Results are generated based on the interpretation selected for each disorder in the tool interface.

1.1 STEPS TO GENERATE SAMPLE NBS RESULTS

HL7 Result Generator tool can be used to generate sample NBS HL7 Result messages using the following steps:

- 1) Navigate to NBS HL7 Result Generator tool

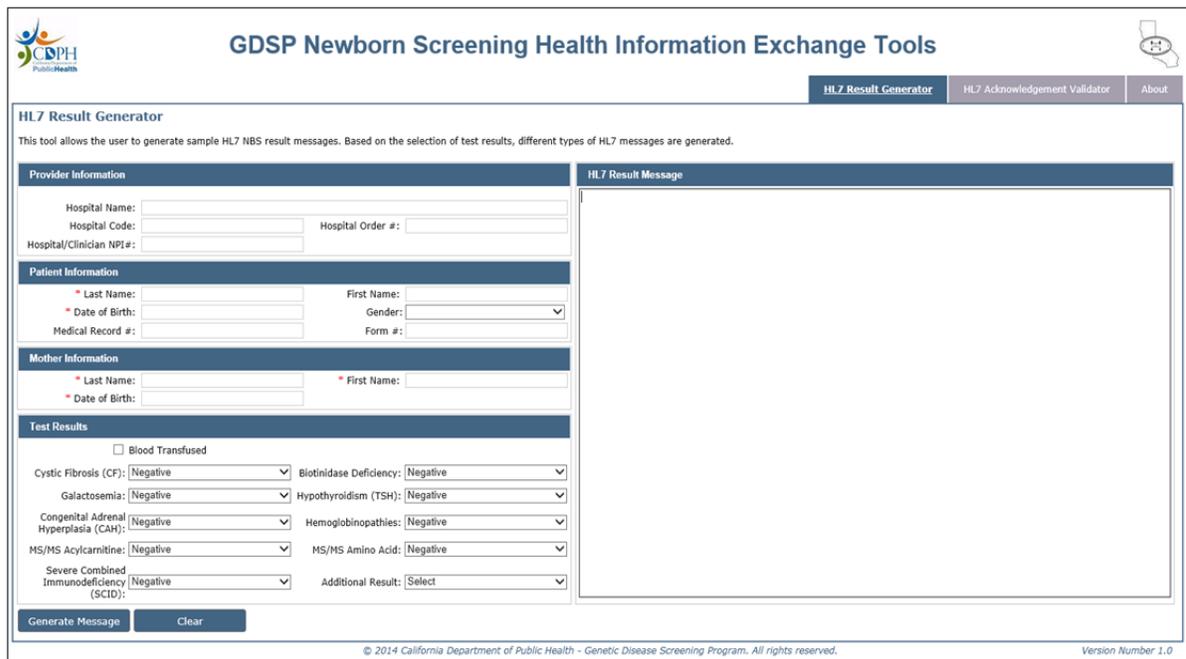


Figure 1.1.1: HL7 Result Generator user interface



- The input fields marked with asterisk (*) are mandatory. Enter the data in the input fields as shown below

HL7 Result Generator

This tool allows the user to generate sample HL7 NBS result messages. Based on the selection of test results, different types of HL7 messages are generated.

Provider Information	HL7 Result Message
Provider Information Hospital Name: Stanford Hospital & Clinic Hospital Code: H001 Hospital Order #: <input type="text"/> Hospital/Clinician NPI #: <input type="text"/>	
Patient Information * Last Name: Ramirez First Name: John * Date of Birth: 02/04/2014 Gender: Male Medical Record #: <input type="text"/> Form #: <input type="text"/>	
Mother Information * Last Name: Ramirez * First Name: Maria * Date of Birth: 09/08/1967	
Test Results <input type="checkbox"/> Blood Transfused Cystic Fibrosis (CF): Negative Biotinidase Deficiency: Negative Galactosemia: Negative Hypothyroidism (TSH): Negative Congenital Adrenal Hyperplasia (CAH): Negative Hemoglobinopathies: Negative MS/MS Acylcarnitine: Negative MS/MS Amino Acid: Negative Severe Combined Immunodeficiency (SCID): Negative Additional Result: Select	
<input type="button" value="Generate Message"/> <input type="button" value="Clear"/>	

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Figure 1.1.2: Sample input to HL7 Result Generator

- Click the 'Generate Message' button. HL7 Message will be displayed in the HL7 Result Message textbox as shown below

HL7 Result Generator

This tool allows the user to generate sample HL7 NBS result messages. Based on the selection of test results, different types of HL7 messages are generated.

Provider Information	HL7 Result Message
Provider Information Hospital Name: Stanford Hospital & Clinic Hospital Code: H001 Hospital Order #: <input type="text"/> Hospital/Clinician NPI #: <input type="text"/>	<pre>MSH ^~\& S19GDSF S19GDSF S19GDSF S19GDSF 11223344*L,M,N L,M,N 20140219015550 ORU^R01^ORU^R01:2:PID 1 ^ANP^MR Ramirez;John^^^^^B 201402040000 M 2106-3^White 1 12186-5^Mex_Hspan^NK1 Maria^Ramirez^M^M^Mother;2592^DUB^DR_#^APT1254^M^SACRAMENTO^CA^95661-4520^USA ^^^^^S16^ORC RE^FormNumber HospOrdNumber KIM^JUFLEANN^NFI Stanford Hospital^VT^4^OBR 1^FormNumber 54089-9^NB Screen Panel Patient AHIC^NFI 2014020600000 KIM^JUFLEANN^NFI 2^FormNumber 57128-1^Newborn Screening Report summary panel^NFI 2014020600000 KIM^JUFLEANN^NFI CE 57718-9^Reason for lab test in Dried blood spot^LN^NFI L1A12421-6^S^Initial screen^LN^NFI CE 57718-9^Sample quality of Dried blood spot^LN^NFI L1A12432-3^S^Acceptable^LN^NFI NFI OBR 3 CE 57130-7^New born screening report - overall interpretation^LN^NFI L1A18949-3^S^Screen 1^LN^NFI OBR 4 CE 57131-8^Newborn conditions with positive markers [Identifier] in Dried blood spot^LN^NFI OBR 5 CE 57720-5^Newborn conditions with equivocal markers [Identifier] in Dried blood spot^LN^NFI OBR 6 IX 57724-7^Newborn screening short narrative summary^LN^NFI Testing Lab - WESTERN CLINICAL^LN^NFI OBR 7 IX 57129-9^Full newborn screening summary report for display or printing^LN^NFI NFI OBR 8 CE 57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN^NFI OBR 9 CE 57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN^NFI OBR 10 CE 57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN^NFI OBR 11 CE 57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN^NFI OBR 12 CE 57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN^NFI OBR 13 CE 57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN^NFI OBR 14 CE 57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN^NFI OBR 15 CE 57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN^NFI OBR 16 CE 57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN^NFI OBR 17 CE 57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN^NFI OBR 18 CE 57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN^NFI OBR 19 CE 57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN^NFI OBR 20 CE 57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN^NFI OBR 21 CE 57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN^NFI OBR 22 CE 57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN^NFI OBR 23 CE 57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN^NFI OBR 24 CE 57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN^NFI OBR 25 CE 57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN^NFI OBR 26 CE 57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN^NFI OBR 27 CE 57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN^NFI </pre>
Patient Information * Last Name: Ramirez First Name: John * Date of Birth: 02/04/2014 Gender: Male Medical Record #: <input type="text"/> Form #: <input type="text"/>	
Mother Information * Last Name: Ramirez * First Name: Maria * Date of Birth: 09/08/1967	
Test Results <input type="checkbox"/> Blood Transfused Cystic Fibrosis (CF): Negative Biotinidase Deficiency: Negative Galactosemia: Negative Hypothyroidism (TSH): Negative Congenital Adrenal Hyperplasia (CAH): Negative Hemoglobinopathies: Negative MS/MS Acylcarnitine: Negative MS/MS Amino Acid: Negative Severe Combined Immunodeficiency (SCID): Negative Additional Result: Select	
<input type="button" value="Generate Message"/> <input type="button" value="Clear"/>	

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Figure 1.1.3: Sample NBS HL7 Result message

4) User can also make different combinations in the Test Results and the HL7 result message will be generated accordingly. Following are some of the scenarios for which HL7 message can be generated:

a) **Blood Transfused:** Select this option if the baby’s blood is transfused. When Blood Transfused checkbox is checked, the Test Results are pre-selected with following values

- Cystic Fibrosis = Negative
- Biotinidase Deficiency= Negative
- Galactosemia = Transfused
- Hypothyroidism = Negative
- Congenital Adrenal Hyperplasia = Negative
- MS/MS Acylcarnitine = Transfused
- MS/MS Amino Acid = Transfused
- SCID = Negative
- *Additional Result* dropdown is disabled
- *Hemoglobinopathies* dropdown list has 3 values that can be selected
 - Disease Questionable
 - HB Uninterpretable
 - HB Variant

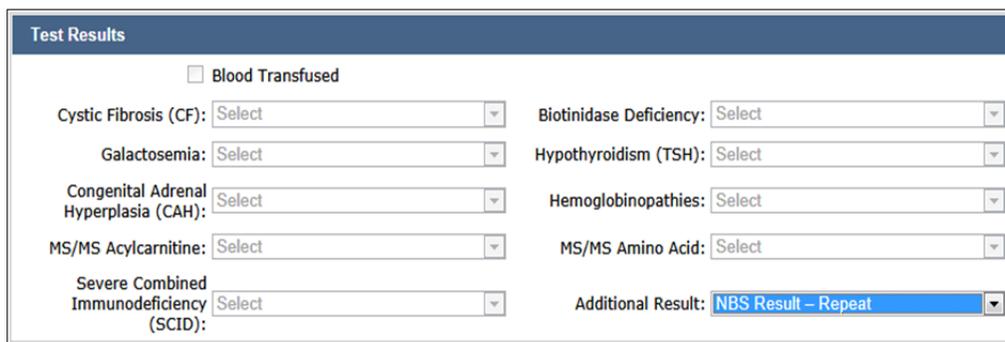
The generated HL7 message will have Specimen Collection date (every OBR.7) 2 days after baby birth and Blood Transfusion Date (every OBR.14) 3 days after Specimen Collection date.

Test Results	
<input checked="" type="checkbox"/> Blood Transfused	
Cystic Fibrosis (CF):	Negative
Biotinidase Deficiency:	Negative
Galactosemia:	Transfused
Hypothyroidism (TSH):	Negative
Congenital Adrenal Hyperplasia (CAH):	Negative
Hemoglobinopathies:	Disease Questionable
MS/MS Acylcarnitine:	Transfused
MS/MS Amino Acid:	Transfused
Severe Combined Immunodeficiency (SCID):	Negative
Additional Result:	Select

Figure 1.1.5: Blood Transfused option in HL7 Result Generator

- b) **Additional Result:** Additional Result types are different from the NBS HL7 results generated for a normal or specific positive case. Structurally the message will be more or less similar but may vary from case to case basis

When any of the Additional Result values is selected, all other fields in Test Results section are disabled shown below.



The screenshot shows a 'Test Results' form with the following fields:

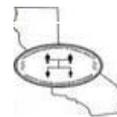
- Blood Transfused
- Cystic Fibrosis (CF): Select
- Galactosemia: Select
- Congenital Adrenal Hyperplasia (CAH): Select
- MS/MS Acylcarnitine: Select
- Severe Combined Immunodeficiency (SCID): Select
- Biotinidase Deficiency: Select
- Hypothyroidism (TSH): Select
- Hemoglobinopathies: Select
- MS/MS Amino Acid: Select
- Additional Result: **NBS Result – Repeat** (highlighted in blue)

Figure 1.1.6: Additional Result option in HL7 Result Generator

Different Additional Results are as follows:

i. NBS Result – Initial (Inadequate Specimen)

- This type of result is generated when the initial specimen collected from a patient was inadequate for testing and deriving interpretations.
- Newborn Screening Report summary panel in HL7 result message will have *Reason for lab test in Dried blood spot* (OBX with LOINC 57721-3) with reason (Observation Value - OBX.5). as “Subsequent screen - for clarification of initial results (not by law or protocol)”.
- Newborn Screening Report summary panel in HL7 result message will have *Sample quality of Dried blood spot* (OBX with LOINC 57718-9) with Observation Value (OBX.5) as “Specimen quantity insufficient for testing”.
- Narrative Summary in HL7 result message will have –
 - Action Identifier as ACTION REQUIRED and
 - Follow-up message as “*** This specimen was inadequate for testing for the following reason”
- Other disorder panels will not be present



ii. NBS Result – Initial (Too Early or Missing Information)

- This type of result is generated if the specimen collection time was within 12 hours of baby's birth.
- Every OBR segment in HL7 result message must have Specimen Collection date (OBR.7) less than 12 hours from baby birth (PID.7).
- Narrative Summary in HL7 result message will have -
 - Action Identifier as ACTION REQUIRED and
 - Follow-up message
- Other disorder panels will be present

iii. NBS Result – Repeat

- This type of result is generated when second specimen is collected since the first specimen collected was inadequate for testing. This result, syntactically is similar to the initial result case
- This result is sent in addition to a previous *NBS HL7 Result – Initial (Inadequate Specimen)* or *NBS Result – Initial (Too Early or Missing Information)*
- Newborn Screening Report summary panel in HL7 result message will have Reason for lab test in Dried blood spot (OBX with LOINC 57721-3) with reason (Observation Value - OBX.5) as “Subsequent screen - for clarification of initial results (not by law or protocol)”
- Newborn Screening Report summary panel in HL7 result message will have Sample quality of Dried blood spot (OBX with LOINC 57718-9) with Observation Value (OBX.5) as “Acceptable”
- Other disorder panels will be present

iv. NBS Result – Repeat (SCID Test)

- This type of result is generated when second specimen is collected to specifically re-test for SCID disorder.
- This result is sent in addition to an Initial NBS Result sent earlier.
- The result will have Newborn Screening Report summary panel with Reason for lab test in Dried blood spot as “Subsequent screen - for clarification of initial results (not by law or protocol”.
- Disorder panel present only for the SCID disorder

v. **NBS Result – CFTR DNA Sequencing**

- This type of result is generated when specimen collected is found to be positive for Cystic Fibrosis disorder.
- This result is sent in addition to an Initial NBS Result sent before.
- Apart from the complete result message, additional CF specific result will be sent.
- Narrative Summary in HL7 result message will have-
 - Action Identifier as ACTION REQUIRED and
 - Follow-up message.
- Disorder panel present only for the Cystic Fibrosis disorder

1.2 COPY AND SAVE RESULTS

- 1) User can copy the generated HL7 message to clipboard by clicking on 'Copy To Clipboard' button. This feature is available only in Internet Explorer web browser.
- 2) User can save the generated HL7 message by clicking on the 'Save' button. The result message is saved to a file in .hl7 format with default filename as *SampleHL7Result*.
- 3) User can clear the form data (input fields and HL7 Result Message) by clicking the 'Clear' button. A popup appears for user confirmation to clear form data. Click on 'Yes' button to clear the form.

2.0 HL7 ACKNOWLEDGEMENT VALIDATOR

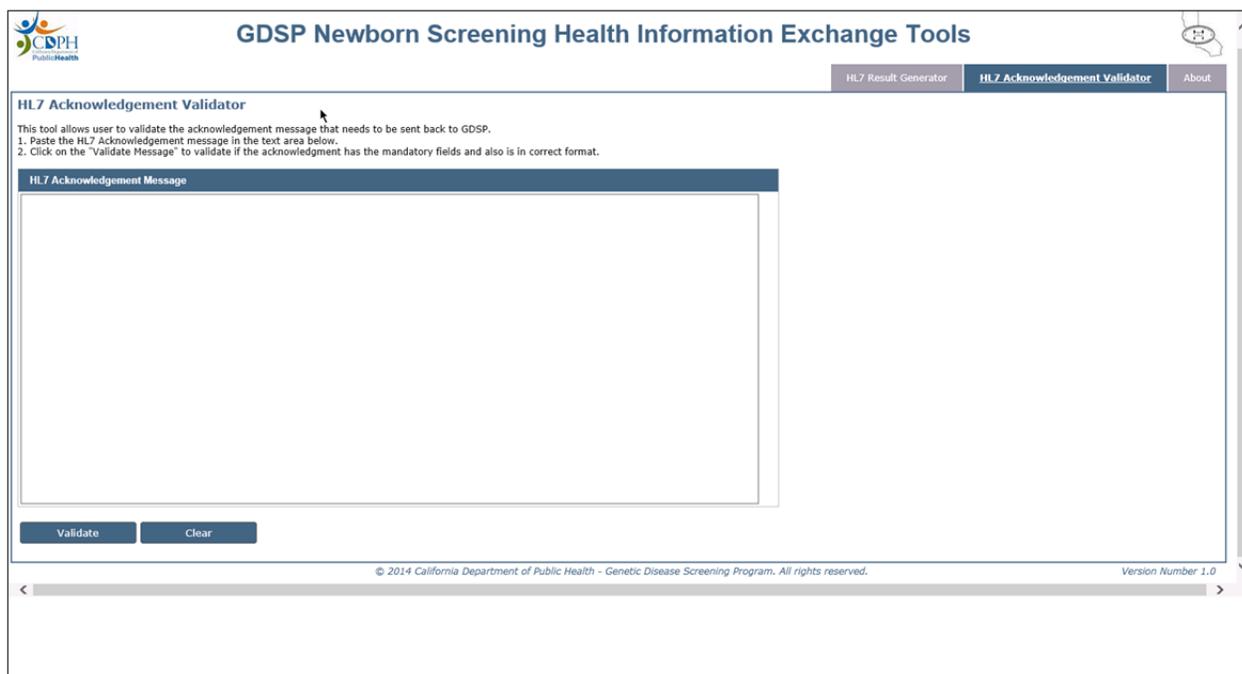
When GDSP sends NBS HL7 Result message to health care provider, it expects to receive an acknowledgement (ACK/NACK) message to confirm successful transmission and processing. GDSP supports the 'Original acknowledgment mode' protocol for message acknowledgement.

HL7 Acknowledgement Validator is a tool to validate HL7 acknowledgements (HL7 2.5.1 format). Refer specifications described in the section 4.0 of *HIE NBS Data Exchange Specification.docx* document from the *Step 2 - Implementation* onboarding packet.

2.1 STEPS TO VALIDATE ACKNOWLEDGEMENT MESSAGES

HL7 Acknowledgement Validator tool can be used to validate HL7 Acknowledgement messages using the following steps:

- 1) Navigate to HL7 Acknowledgement Validator tool.



The screenshot shows the user interface for the HL7 Acknowledgement Validator tool. At the top, there is a navigation bar with the CDPH logo and the title "GDSP Newborn Screening Health Information Exchange Tools". Below this, there are three tabs: "HL7 Result Generator", "HL7 Acknowledgement Validator" (which is selected), and "About". The main content area is titled "HL7 Acknowledgement Validator" and contains the following text: "This tool allows user to validate the acknowledgement message that needs to be sent back to GDSP. 1. Paste the HL7 Acknowledgement message in the text area below. 2. Click on the 'Validate Message' to validate if the acknowledgment has the mandatory fields and also is in correct format." Below this text is a large text area labeled "HL7 Acknowledgement Message". At the bottom of the text area are two buttons: "Validate" and "Clear". The footer of the interface contains the text: "© 2014 California Department of Public Health - Genetic Disease Screening Program. All rights reserved. Version Number 1.0".

Figure 2.1.1: HL7 Acknowledgement Validator user interface

- 2) Paste the acknowledgement in the HL7 Acknowledgement Message text area. Refer to the sample acknowledgement messages in the *Step 2 - Implementation* onboarding packet.

- Click on the Validate button at the bottom of the page. This brings up the validation result message on top of the HL7 Acknowledgement Message panel as shown below.

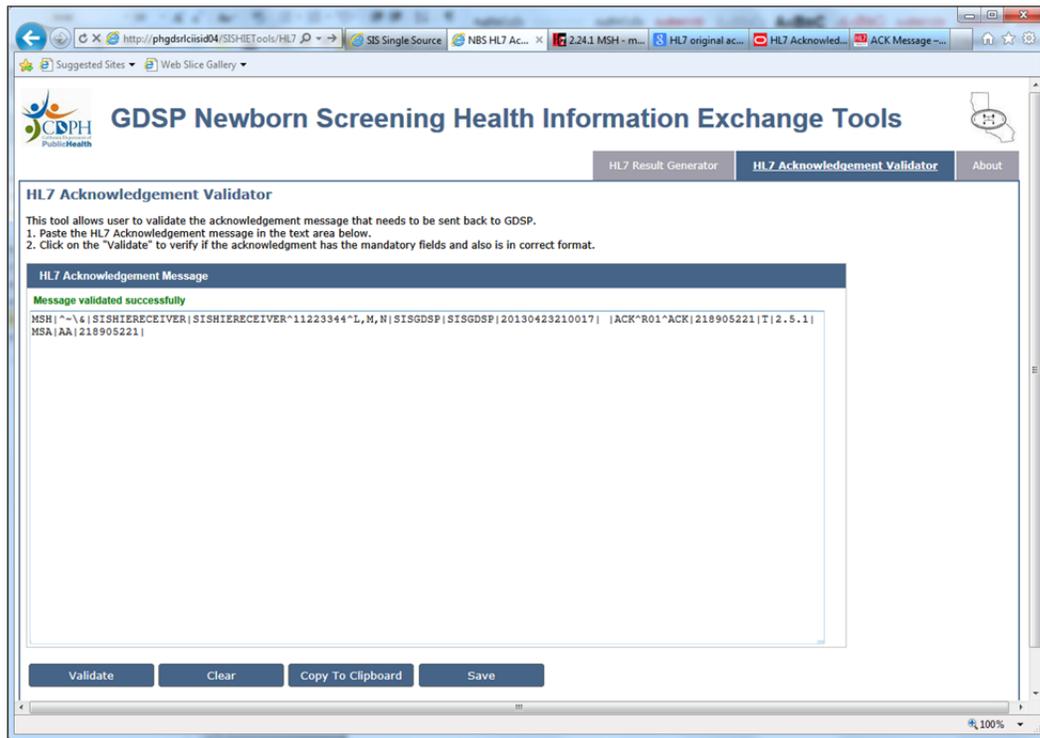


Figure 2.1.2: Successful validation of HL7 Acknowledgement

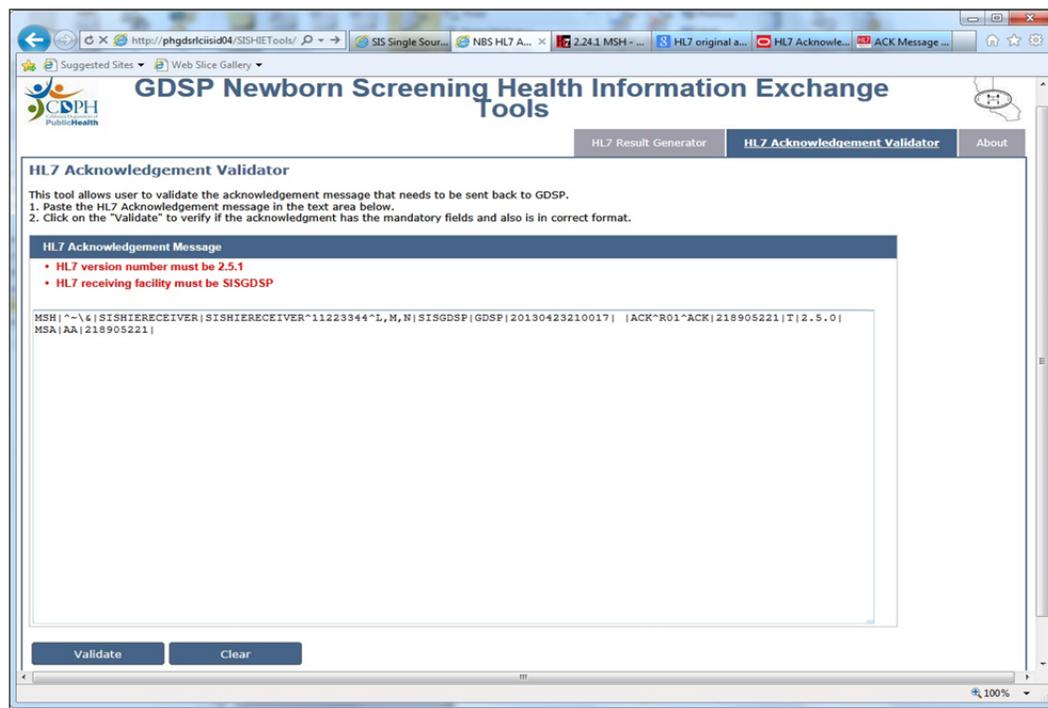


Figure 2.1.3: Unsuccessful validation of HL7 Acknowledgement

2.2 COPY AND SAVE ACKNOWLEDGEMENT

- 1) User can copy the generated HL7 message to clipboard by clicking on 'Copy To Clipboard' button. This feature is available only in Internet Explorer web browser.
- 2) User can save the validated acknowledgement by clicking the 'Save' button. The acknowledgement message is saved to a file in .hl7 format with default filename as *SampleHL7Ack*.
- 3) User can clear the acknowledgement message by clicking the 'Clear' button. A popup appears for user confirmation to clear form data. Click 'Yes' button to clear the form.